

REMARKS

Claims 1, 3 to 5 and 8 to 13 are all the claims pending in the application, prior to the present amendment.

Claims 1, 3-5 and 8 have been rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent 4,247,568 to Carrington et al.

Applicants submit that Carrington et al do not disclose or render obvious the subject matter of claims 1, 3-5 and 8 and, accordingly, request withdrawal of this rejection.

The present invention as set forth in claim 1 is directed to a method for preparing a water-soluble glucose polymer having an ion-exchanging ability comprising the steps of drying a mixed aqueous solution containing a raw glucose polymer and a polyvalent carboxylic acid to thus form a uniform powdery mixture and then subjecting the powdery mixture to a heat treatment. The raw glucose polymer and the polyvalent carboxylic acid are first dissolved in water to form an aqueous solution, the raw glucose polymer is at least one member selected from the group consisting of oxidized starch, starch hydrolyzates, hydrogenated starch hydrolyzates and digestion-resistant starch hydrolyzates, and the average degree of polymerization thereof ranges from 4 to 123. In the method of the present invention, the temperature of the powder upon the heat-treatment ranges from 100 to 125° C.

Carrington et al disclose a process for preparing a non-digestible food additive which comprises the step of heating a mixture of starch or starch hydrolysate and carboxylic acid at a temperature of 140 to 220°C. See, column 2, lines 1-6, and claim 1. The food additives in Carrington et al are disclosed as and taught to be at least partially insoluble in water. See, e.g., column 5, lines 16-24 and Examples 1-6.

Carrington et al further state that the mixture of starch or starch hydrolysate and carboxylic acid may be prepared in a number of ways before heating at 140 to 220°C. For example, solid starch materials and the edible acid in powder form may be mixed and then dried, an aqueous solution of the edible acid may be sprayed onto starch or starch hydrolysate powder, or starch or starch hydrolysate powder may be dispersed in an aqueous solution of the edible acid and the slurry then dried. Column 4, lines 19-33.

The Examples similarly illustrate these diverse methods. For example, Example 1 describes that raw maize starch powder was blended with citric acid powder and the mixture was then heated at 180 °C. Column 5, lines 45-52. Additionally, Example 5 describes that an aqueous solution of citric acid was sprayed onto the agitated starch powder to give a uniform distribution of citric acid in the starch powder and the mixture was then heated at 180 °C. Column 6, lines 24-35. Example 6 describes that the starch powder was dispersed in water, citric acid was added to this dispersion, and the slurry was then dried and heated to 180°C.

Applicants submit that the presently claimed invention is neither anticipated by nor rendered obvious by the teachings of Carrington et al.

First, as mentioned above, the purpose of Carrington is to provide food additives that are at least partially insoluble in water, as opposed to the presently claimed method for producing a water-soluble product.

In addition, Carrington et al notably do not teach or suggest that it is necessary to dissolve the starch or starch hydrolysate in water to attain the uniformity of powdery mixture and then to heat the powdery mixture at 100 to 125°C to obtain a water-soluble product.

With regard to the temperature range presently claimed, Carrington et al specifically state and claim that a temperature of from 140 to 220°C is used in the Carrington et al process.

Therefore, the presently claimed temperature range is not anticipated by Carrington et al.

In addition, there is nothing within Carrington et al that would motivate one of ordinary skill in the art to use a reduced temperature and thereby allegedly arrive at applicants' invention. Carrington et al are entirely concerned with using a heating step that heats the composition therein at a temperature of from 140 to 220°C. Therefore, applicant submits that this element of the present invention is not rendered obvious by Carrington.

Additionally, Carrington et al fail to teach the importance of the presently claimed temperature range, for if the heating temperature is not in the range of 100 to 125°C, the presently claimed water-soluble glucose polymer is not created. Applicants specifically note that if the heating temperature is lower than 100°C, an esterification reaction does not proceed, while if it is higher than 125°C, water-insoluble matter is generated, as shown on page 15, Table 1 of the specification. Thus, applicants submit that this element of the present claims is neither anticipated by nor rendered obvious by Carrington et al.

Finally, the present claims are not anticipated by or rendered obvious by Carrington et al for the following reason: if a raw glucose polymer and a polyvalent carboxylic acid are not first dissolved in water to form an aqueous solution as recited in claim 1, the water-insoluble glucose polymer of the present claims is not created. Applicants show this in Comparative Example 1, on pages 18-19 of the specification. Carrington et al do not disclose any preference for this method of mixing materials, and even if Carrington et al did disclose any preference for this method of mixing materials, Carrington et al fail to disclose that this method is necessary to form the water-insoluble glucose polymer of the present invention. Therefore, applicants submit that

this element of the claimed invention is neither anticipated by nor rendered obvious by Carrington.

In the Office Action, the Examiner refers to column 4, line 21 of Carrington et al as disclosing the heating of a dry mixture of starch hydrozylate and di- or tricarboxylic acid at 140°C to 220°C which, according to the Examiner, covers the temperature range disclosed in claim 1.

Applicants disagree with the Examiner's assertion that the temperature of 140°C to 220°C disclosed in Carrington et al covers the temperature range set forth in claim 1.

As noted above, claim 1 recites a temperature range of 100 to 125°C. The temperature range of 140°C to 220°C in Carrington et al is different from and does not cover the 100 to 125°C range of claim 1. Accordingly, applicants disagree with the Examiner's assertion that the temperature of 140°C to 220°C in Carrington et al covers the temperature range disclosed in claim 1. The Examiner does not provide any logical reason why or how a temperature range of 140°C to 220°C covers a temperature range of 100 to 125°C which has as its highest temperature a temperature that is lower than the lowest temperature of the Carrington et al range of 140°C to 220°C.

With respect to the difference in temperature that applicants argued, the Examiner states that the present specification teaches that the temperature range can be as high as 160°C, which according to the Examiner covers part of the temperature range disclosed in the Carrington et al patent. The Examiner states that if criticality is asserted for proportions or ranges, the specification must not disclose them as merely preferred. The Examiner then cites two previous legal decisions in support of his position.

The two decisions are *Hays v. Reynolds* and *In re Bourdon*. Applicants have reviewed these decisions and submit that they are inapplicable to the present case and are not controlling.

In particular, the *In re Bourdon* decision, which was issued by the CCPA in 1957, was discussed later by the CCPA in *In re Saunders*, 170 USPQ 213 (CCPA 1971). The *In re Saunders* decision disagreed with the reasoning in *In re Bourdon* and, in effect, overruled *In re Bourdon*. The *Hays* decision was issued in 1965 by the District Court for the District of Columbia, and does not set forth any reason in support of its statement that the specification must not disclose proportions or ranges as merely preferred if applicants are asserting criticality for those proportions or ranges. In view of the *Saunders* decision, applicants submit that the *Hays* decision is not controlling.

Further, the Examiner's reference to the disclosure of a temperature in the present specification as high as 160°C appears to be an attempt to use the present specification to show equivalence between the claimed range of 100 to 125°C and the range of 140 to 220°C disclosed in the Carrington et al patent. As the case law makes clear, however, an applicant's specification cannot be relied upon as prior art to show equivalence.

Accordingly, applicants submit that the disclosure of 140 to 220°C in Carrington et al does not suggest or render obvious the 100 to 125°C temperature recited in the present claims.

With respect to applicants' argument that the present claims recite water soluble products, whereas the products in Carrington et al are water insoluble, the Examiner states that Carrington et al disclose products that may be soluble in water. The Examiner particularly refers to the sentence bridging columns 4 and 5 in the Carrington et al patent, which discusses the further treatment of the products, and states that the products may be dissolved "if soluble, in

water...”. The Examiner relies on this statement to show that the products of Carrington et al may be soluble in water.

In response, applicants point out that Carrington et al simply state that the product is dissolved, if soluble, in water, but Carrington et al do not teach or suggest any specific method for the preparation of a water-soluble glucose polymer. All the polymers specifically disclosed in Carrington et al are water-insoluble polymers.

Thus, a person of ordinary skill in the art would not conceive and reach the claimed invention based on the disclosures of Carrington et al.

In addition, the Examiner states that applicants have argued that Carrington et al do not disclose a step of first dissolving the glucose polymer and polyvalent carboxylic acid in water to form an aqueous solution. The Examiner argues that this step is a preferred step of the method disclosed in the Carrington et al patent, as disclosed at column 4, lines 29-33 of Carrington et al.

The disclosure at column 4, lines 29-33 of Carrington et al, however, does not refer to the dissolving of the glucose polymer, but rather states that the “starch or starch hydrozylate powder is dispersed in an aqueous solution of the edible acid.” Thus, this portion of Carrington et al does not state that the glucose polymer is dissolved in water.

With respect to claim 5, the Examiner states that the ion exchangeability index set forth in claim 5 appears to be an inherent property of the starch hydrozylates disclosed in the Carrington et al patent.

Applicants disagree that the ion exchangeability index in claim 5 is an inherent property of the starch hydrozylates disclosed in the Carrington et al patent

In particular, the ion-exchanging ability index Y, as disclosed in the present specification at page 12, is represented by the formula

$Y = A \times B$, where A is an amount of the linked polyvalent carboxylic acid, and B is an esterification index.

Applicants point out that the ion-exchanging ability index Y is measured for a water-soluble glucose polymer, that is, the final product from which water-insoluble matter has been removed, but not for a water-insoluble polymer.

Table 1, at page 15 of the present specification, shows the effect of powder temperature as follows.

Temp. of powder	Heating time (min)	Ion-exchanging ability index	Esterification index	Insoluble matter (%)*	Remarks
90°C	900	0	0	0	(1)
100°C	900	0.12	2.0	0	(2)
110°C	900	0.20	2.0	0	(2)
120°C	400	0.26	2.0	0	(2)
135°C	300	0.29	1.9	49.4	(3)
160°C	120	0.34	1.6	73.5	(3)
170°C	--	--	--		(4)

Note:

* Insoluble matter (%) = $100 \times (\text{total dry weight of insoluble matter in final product} / \text{total dry weight of starting materials})$

- (1) The esterification reaction did not proceed.
- (2) There was not observed any water-insoluble matter.
- (3) There was observed generation of water-insoluble matter.
- (4) The reactants were molten and could not hold their powdery states.

As seen from the table, the ion-exchanging ability index Y depends on the powder temperature at which the final product was prepared. At a powder-heating temperature of 170°C, the reactants were molten through heating and they could not maintain their powdery states. The glucose polymers prepared at 135°C and 160°C generated water-insoluble matter, while those prepared at 100°C, 110°C and 120°C did not generate water-insoluble matter.

The reaction in Examples 2 to 4 of Carrington et al was conducted at 180°C, which is much higher than the temperature range of 100 to 125°C specified in the presently claimed invention.

At such a high temperature of 180°C, the reactants would be molten and could not hold their powdery states. Carrington et al state that "The products in each case contained less than 10% water-soluble material. After treatment as in Example 1, the final products were in each case pale cream-colored, insoluble in water and only 1% hydrolyzable by α -amylase." See, col. 6, lines 17-21.

In addition, Carrington et al state in Example 1 that "The dried powder was then blended with anhydrous citric acid powder The mixture was then heated in a glass flask at 180°C ... for 3 hours. Samples taken at intervals during the heating period showed that proportion of the product hydrolyzable by α -amylase was progressively reduced until at the end of the period it was only 4%. The proportion of water-soluble material was also progressively reduced to 10%." See, col. 5, lines 48-59.

The method of the present invention is characterized in that a raw glucose polymer and a polyvalent carboxylic acid are once converted into a mixed aqueous solution, the aqueous solution is subsequently dried to give uniform powder and then the resulting uniform powder is heat-treated at 100°C to 125°C.

In Comparative Example 1 in the present specification, a simple mixed powder of a raw glucose polymer and a polyvalent carboxylic acid was heated and the results were compared with those of the method of the present invention. More specifically, the ingredients used in Comparative Example 1 were reacted under the same conditions used in Example 1.

As a result, it was found that uniform powder of the present invention provided a glucose polymer having an ion-exchanging ability index of 0.26 and an esterification index of 2.0, while the presence of any linkage between the polyvalent carboxylic acid and the raw glucose polymer was not confirmed at all for the simple mixed powder as a comparative sample.

This result clearly indicates that the uniform powder of the present invention is highly reactive.

Thus, according to the method disclosed in Carrington et al, it is not possible to produce a water-soluble glucose polymer. In addition, it is not possible to determine the ion-exchanging ability index of the water-insoluble products prepared in Carrington et al according to the method for determining the ion-exchanging ability index disclosed in the present specification because they are not water-soluble.

Accordingly, the ion-exchanging ability index set forth in claim 5 is not an inherent property of the starch hydrolyzates disclosed in Carrington et al.

Applicants emphasize the following remarkable advantages of the present invention:

(1) the products of the invention do not contain water-insoluble matter, while the comparative products contain a large amount of insoluble matter (49.4% at 135°C and 73.5% at 160°C as disclosed in Table 1 of the present specification), and

(2) the process is very simple and it is not necessary to purify the final product because it does not contain water-insoluble matter.

In view of the above, applicants submits that the present invention is neither anticipated by nor rendered obvious by Carrington et al. Therefore, applicants requests reconsideration and withdrawal of the rejection based on Carrington et al.

With respect to the Information Disclosure Statement filed on July 27, 2004, and the document AT 342079, the Examiner states that the English language European Search Report which cites this document is not in the file of the USPTO.

Applicants' undersigned counsel has reviewed the "PAIR" file of the USPTO, and has determined that the European Search Report, in fact, is in the file at the USPTO. The Examiner apparently did not recognize that the document is in the file. Accordingly, applicants request the Examiner to review the file and consider and make of record the AT 342079 document.

The Examiner states that claims 9-13 drawn to a non-elected invention should be canceled or other appropriate action taken when filing a response to the final rejection. In response, applicants have canceled claims 9-13 in the present Amendment.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Sheldon I. Landsman/

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Sheldon I. Landsman
Registration No. 25,430

Date: October 15, 2007